K071288

JUL 19 2007

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
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Colleen Boswell - Contact Person

Date Summary Prepared: June 2007

Device Name:

- Trade Name - *KaVo QUATTROcare Modified*
- Common Name - Dental Handpiece Lubricant/Cleaner
- Classification Name - Dental Handpiece and Accessories, per 21 CFR § 872.4200
-

Devices for Which Substantial Equivalence is Claimed:

- Kaltenbach & Voigt GmbH, *KaVo QUATTROcare*

Device Description:

The *KaVo QUATTROcare Modified* is a unit that uses an aerosol product based upon hydrocarbon propellants with a lubricant for use in the routine maintenance (cleaning and lubrication) of dental handpieces prior to sterilization. The lubricant is housed within a spray can and is a component of the unit. The *KaVo QUATTROcare Modified* device was modified to enhance the secure fit of the lubricant spray can to the unit through the utilization of two independent sealing systems - the screw can sealing and an additional O-ring sealing in the connector.

Intended Use of the Device:

The intended use of the *KaVo QUATTROcare Modified* is for internal cleaning, i.e, purging of old lubricant, for the maintenance of rotating dental and surgical instruments. The *KaVo QUATTROcare* spray can is a component of the *KaVo QUATTROcare* unit and is specifically designed to fit this unit only. The lubricant spray can is unable to be used manually.

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Substantial Equivalence:

The *KaVo QUATTROcare Modified* is substantially equivalent to other legally marketed devices in the United States. The *KaVo QUATTROcare Modified* functions in a manner identical to and is intended for the same use as the original version of the *KaVo QUATTROcare* manufactured by Kaltenbach & Voigt GmbH.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2007

Kavo America Corporation
C/O Ms. Colleen Boswell
Vice President, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K071288
Trade/Device Name: KaVo QUATTROcare
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: May 7, 2007
Received: May 8, 2007

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071288

Device Name: *KaVo QUATTROcare*

Indications For Use:

KaVo QUATTROcare is a unit intended for internal cleaning, i.e, purging of old lubricant, for the maintenance of rotating dental and surgical instruments. The *KaVo QUATTROcare* spray can is a component of the *KaVo QUATTROcare* unit and is specifically designed to fit this unit only. The lubricant spray can is unable to be used manually.

NOTE: The *KaVo QUATTROcare* should be used with only pre-cleaned dental handpieces and before they are sterilized.

Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R.S. Betz DDS for Dr. Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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